K111478

Special 510(k) Summary of Safety and Effectiveness:
Line Extension to Stryker Spine Spinal Systems:
Xia, Xia 3, Xia 4.5, Radius, Mantis and Mantis Redux Systems

AUG - 4 2011

Proprietary Name:	Power Adaptor Instrument Accessory
Common Name:	Spinal Fixation Appliances, Instrument Accessory
Classification Name and Reference:	Pedicle Screw Spinal System, 21 CFR §888.3070 (b) (1) & (b) (2)
Device Product Code:	NKB, MNH, MNI
Proposed Regulatory Class:	Class III
For Information contact:	Curtis Truesdale Regulatory Affairs Project Manager 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8296 Fax: (201) 760-8496 Email: Curtis.Truesdale@Stryker.com
Date Summary Prepared:	August 3, 2011
Predicate Devices	▪ Stryker Spine XIA Spinal Systems, K060361; ▪ Stryker Spine XIA 3 Spinal System, K091291; ▪ Stryker Spine XIA 4.5 Spinal System, K092605; ▪ Stryker Spine RADIUS Spinal System, K101144; ▪ Stryker Spine MANTIS Spinal System, K102235; ▪ Medtronic LEGEND Power Adaptor, K101168;

Description of Device Modification

The line extension, which is the subject of this 510(k), consists of the addition of a power adaptor instrument accessory. This adaptor instrument is intended to facilitate the insertion of pedicle screws using powered instrumentation. This 510(k) supports a labeling update to include the option for pedicle screw insertion using powered instrumentation (in addition to the existing manual insertion technique). To facilitate the insertion of pedicle screws using the power technique, the use of the Stryker Spine Power Adaptor is intended for exclusive use with the Stryker Instruments Hudson Modified Trinkle Adaptor and the RemB Corded Driver. The adaptors serve as a mechanical interface between the power driver and screwdriver instrument. When the adaptors are attached, the RemB Corded Driver provides appropriate power to rotate screw drivers for the insertion of pedicle screws. No changes have been made to the indications for use of the associated thoracolumbar spinal implant systems: Xia Spinal System (Xia Stainless Steel, Xia II, Xia Anterior, and Xia Precision), Xia 3 Spinal System, Xia 4.5 Spinal System, Radius Spinal System and Mantis Spinal System. The indications for use of each spinal system remain consistent with their most recent 510(k) clearance.

Intended Use and Indications for Use

To facilitate the placement of pedicle screws using the power technique, the use of the Stryker Spine Power Adaptor is intended for exclusive use with the Stryker Instruments Hudson Modified Trinkle Adaptor and the RemB Corded Driver. When the adaptors are attached, the RemB Corded Driver provides power to rotate screw drivers for inserting of pedicle screws.

Pedicle screws from select Stryker Spine implant systems may be implanted in the skeletally mature non-cervical spine using powered instrumentation. The systems include the family of Xia Spinal Systems (Xia Stainless Steel, Xia II, Xia Anterior, and Xia Precision), Xia 3 Spinal System, Xia 4.5 Spinal System, Radius Spinal System and Mantis Spinal Systems.

The Xia® Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The XIA® 4.5, XIA® 3, Radius® Spinal Systems are intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); Spondylolisthesis; Trauma (i.e., fracture or dislocation); Spinal Stenosis; Curvatures (i.e., scoliosis, kyphosis, and/or lordosis); Tumor; Pseudoarthrosis; and Failed previous fusion.

The MANTIS® Spinal System and MANTIS® Redux Spinal System is intended for percutaneous, posterior, non-cervical pedicle and non-pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; Pseudoarthrosis; and failed previous fusion.

Summary of the Technological Characteristics

A Risk assessment was conducted and identified the appropriate testing plan. Bench testing activities consisted of fatigue and functional compatibility testing performed with the power adaptor instrument over a simulated usage period. The Testing results demonstrated that the subject instrument can withstand screw loading and screw insertion during normal use without loss of function. Bench testing results also demonstrated that the power adaptor instrument is compatible with existing screwdriver instruments. To further evaluate the safety of the power pedicle screw insertion technique using the instrumentation mentioned herein, the power adaptor and associated instrumentation were tested under simulated use conditions to evaluate the quality/accuracy of screw placement. The Stryker Spine Adaptor has similar technological characteristics as the previously 510(k) cleared Medtronic LEGEND Power Adaptor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG - 4 2011

Stryker Corporation
% Ms. Tiffani Rogers
2 Pearl Court
Allendale, New Jersey 07401

Re: K111478
Trade/Device Name: Stryker Spine Power Adaptor
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: July 01, 2011
Received: July 06, 2011

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111478

Device Name: Stryker Spine Power Adaptor Instrument

Intended Use:
To facilitate the placement of pedicle screws using the power technique, the use of the Stryker Spine Power Adaptor is intended for exclusive use with the Stryker Instruments Hudson Modified Trinkle Adaptor and the RemB Corded Driver. When the adaptors are attached, the RemB Corded Driver provides power to rotate screw drivers for inserting of pedicle screws.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jonathan C. Kahn 8/3/11

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111478